BLANK ROME LLP
ANN B. LAUPHEIMER (*Pro Hac Vice*)
laupheimer@blankrome.com
JOSEPH M. PROFY (*Pro Hac Vice*)
profy@blankrome.com
130 North 18th Street
Philadelphia, Pennsylvania 19103-6998
Telephone: 215.569.5500
Facsimile: 215.569.5555

BLANK ROME LLP
W. SCOTT SIMMER (*Pro Hac Vice*)
simmer@blankrome.com
HARDY VIEUX (*Pro Hac Vice*)
vieux@blankrome.com
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037
Telephone: 202.772.5800
Facsimile: 202.772.5858

Attorneys for Plaintiff,
KAISER FOUNDATION HEALTH PLANS, INC.

UNITED STATES COURT

CENTRAL DISTRICT OF CALIFORNIA — WESTERN DIVISION

KAISER FOUNDATION HEALTH PLAN, INC.

Plaintiff,

vs.

ABBOTT LABORATORIES,

Defendant.

CASE NO. CV 02-02443-JFW (FMOx)

(ASSIGNED TO HON. JOHN F. WALTER)

KAISER'S STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW

Date: October 5, 2009
Time: 1:30p.m.
Place: Courtroom 16

Pretrial Conference Date: January 8, 2010
Trial Date: January 26, 2010

Pursuant to this Court's 2nd Amended Scheduling and Case Management Order of June 1, 2009, Plaintiff Kaiser Foundation Health Plan, Inc. ("Kaiser") submits this

Statement of Uncontroverted Facts and Conclusions of Law in support of Kaiser's Motion for Partial Summary Judgment as to Abbott's Monopoly Power.

STATEMENT OF UNCONTROVERTED FACTS

UNDISPUTED FACT	SUPPORTING EVIDENCE
1. Abbott Laboratories ("Abbott") was the only supplier of terazosin hydrochloride ("terazosin"), brand-name Hytrin, up until August 1999.	Request for Judicial Notice ¶ 1, Ex. 1 (Order Granting Pls.' Mot. for Partial Summ. Judgment and Denying Def. Zenith's Mot. for Summ. Judgment at 8, In re Terazosin Hydrochloride, No. 99-MDL-1317 (S.D. Fla. Dec. 13, 2000)[hereinafter Ex. 1]).
2. Prior to August 1999, Abbott charged Kaiser between 67 and 70 cents per tablet of brand-name Hytrin.	Request for Judicial Notice ¶ 2, Ex. 2 (Parties' Jt. Stip. of Facts Not in Dispute at 27, ¶ 170, In re Terazosin Hydrochloride, No. 99-MDL-1317 (S.D. Fla. July 16, 2004) [hereinafter Ex. 2].
3. Abbott knew that it stood to lose a significant amount of sales when generic terazosin entered the market.	Declaration of Hardy Vieux ("Vieux Decl.") ¶1, Ex.A (Compendium of Generic Substitution Models and Other Analyses).
4. Abbott entered into an agreement with Geneva Pharmaceuticals ("Geneva") on April 1, 1998, whereby Abbott paid Geneva $4.5 million a month not to come to market with generic terazosin.	Request for Judicial Notice ¶ 1, Ex. 1.

5. Geneva entered the market with a generic version of terazosin hydrochloride in August 1999.	Request for Judicial Notice ¶ 2, Ex. 2.
6. After Geneva entered the market in August 1999, Abbott offered to sell Hytrin to Kaiser at 10 cents per tablet.	Request for Judicial Notice ¶ 2, Ex. 2.
7. One year after generic terazosin entered the market, Abbott's Hytrin sales dropped over 75%—just as Abbott had predicted would occur.	Vieux Decl. ¶ 2, Ex. B (Tab 10 from Expert Rpt. of Dr. Ernst Berndt (Nov. 17, 2003), ¶ 3, Ex. C (Expert Rpt. of Dr. James Langenfeld at 33-34.)

STATEMENT OF CONCLUSION OF LAW

UNDISPUTED CONCLUSION OF LAW	SUPPORTING EVIDENCE
1. Direct evidence of supracompetitive prices or actual exclusion of competition establishes monopoly power as a matter of law.	(Am. Tobacco Co. v. United States, 328 U.S. 781, 810-11 (1946)); (Conwood Co. L.P. v. U.S. Tobacco Co., 290 F.3d 768, 783 n.2 (6th Cir. 2002)); (Byars v. Bluff City News Co., 609 F.2d 843, 850 (6th Cir. 1979)).

ADDITIONAL UNCONTROVERTED FACTS

ADDITIONAL FACT	SUPPORTING EVIDENCE
1. Under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), a drug manufacturer seeking the	21 U.S.C. § 355; Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d 1033, 1036 (9th Cir. 2009); (Ex. 2at 2-3 ¶¶ 5, 7-8.)

ADDITIONAL FACT	SUPPORTING EVIDENCE
Food and Drug Administration's approval to sell a generic version of a patented, brand-name drug may file an Abbreviated New Drug Application.	
2. An ANDA applicant who, in connection with its application, certifies that the patent of the brand-name drug is either invalid or will not be infringed by the generic drug must notify the holder of the brand-name patent of its ANDA.	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1037; see also 21 U.S.C. § 355(j)(2)(A)(vii); (Ex. 2 at 3, ¶ 9).
3. Certification entitles the ANDA applicant to a 180-day period of exclusive distribution of the generic drug upon its approval by the FDA.	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1037; see also 21 U.S.C. § 355(j)(5)(B)(iv); (Ex. 2 at 4, ¶ 13).
4. By filing an infringement suit within the forty-five-day period, the holder of the brand-name patent generally delays what would otherwise have been automatic FDA approval for a period of thirty months commonly referred to as the "automatic	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1037; (see also Ex. 2 at 3-4, ¶ 12).

ADDITIONAL FACT	SUPPORTING EVIDENCE
stay."	
5. Kaiser is a health care provider that purchases large quantities of prescription drugs from manufacturers such as Abbott.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1037.
6. Abbott develops and manufactures brand-name drugs, including Hytrin.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1037-38; (see also Ex. 2 at 26, 27, ¶¶ 165, 173.)
7. Non-party Geneva Pharmaceuticals manufactures generic drugs, including generic terazosin.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1038; (see also Ex. 2 at 28, ¶ 174.)
8. After first patenting terazosin in 1977, Abbott continued to patent other forms of terazosin.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1038; (see also Ex. 2 at 9-11, ¶ 41-50); Request for Judicial Notice ¶ 4, Ex. 4 (Omnibus Order on Six Mots. For Summ. Judgment re: Pls.' Section One (and Analogous) Claims, In re Terasozin Hydrochloride, No. 99-MDL-1317 (S.D. Fla. Jan. 5, 2005)).
9. Abbott filed Patent 5,504,207 in October of 1994, seeking to patent a different crystalline polymorph of terazosin just as its other, active patents were set to expire.	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1038; (see also Ex. 2 at 10-11, ¶ 49; Ex. 4 at 7-9).
10. With respect to "prior art," Abbott furnished an abstract of an earlier Japanese patent	(See Ex. 2 at 22-23, ¶¶ 133-37, 139).

ADDITIONAL FACT	SUPPORTING EVIDENCE
application, but failed to furnish an English translation of the Japanese patent application that discloses the same form of terzsozin Abbott sought to be covered by the '207 patent.	
11. Abbott disclosed prior sales, justifying its patent application notwithstanding these sales on its nuanced legal theory that the "on-sale bar" does not apply when the purchasers in prior sales did not know that the version of the terazosin they had purchased was the specific crystalline polymorph Abbott sought to cover in the '207 patent application.	(See Ex. 2 at 23-24, ¶¶ 141-42).
12. The '207 patent was issued on April 2, 1996.	See Ex. 2 a at 10-11, 23-24, ¶¶ 49, 141-42; Ex. 4 at 7).
13. Between 1993 and 1998, Geneva and several other generic manufacturers filed a series of ANDAs seeking FDA approval of generic versions of terazosin.	552 F. 3d at 1039-40; (see also Ex. 2 at 7-8, ¶¶ 28-39).
14. Geneva, which filed ANDAs for both a tablet and capsule form of	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1039-40; (see also Ex. 2 at 18-22).

ADDITIONAL FACT	SUPPORTING EVIDENCE
generic terazosin, and the other generic drug manufacturers certified that Abbott's patents, including the '207 patent, were either invalid or were not infringed by the generic versions of the drug and provided notice to Abbott.	
15. Abbott had forty-five days from the notice of each certification to file infringement suits under the Hatch-Waxman Act.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1037 (citing 21 U.S.C. § 355 (j)(5)(B)(iii)); (see also Ex. 2 at 3-4, ¶ 12).
16. Abbott brought patent infringement suits against the generic manufacturers, including an infringement suit against Geneva in response to the ANDA it had filed for a tablet form of generic terazosin ("Tablet ANDA"), in which Abbott contended that the generic version at issue in the Tablet ANDA would violate its '207 patent.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1040; (see also Ex. 2 at 18, ¶ 108; Ex. 4 at 8).
17. Abbott neglected to file an infringement suit in response to the ANDA Geneva had filed for a	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1040; (see also Ex. 2 at 18, ¶ 108, 110; Ex. 4 at 8).

ADDITIONAL FACT	SUPPORTING EVIDENCE
capsule form of generic terazosin ("Capsule ANDA"), which would likewise have infringed the '207 patent.	
18. As a result of Abbott's failure to file a timely infringement suit under the Hatch-Waxman Act with respect to the Capsule ANDA, Abbott forfeited the automatic stay of FDA approval, and the FDA approved Geneva's capsule version of generic terazosin on March 30, 1998.	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1037, 1040; (see also Ex. 2 at 24, 28, ¶¶ 145-46, 176; Ex. 4 at 8).
19. On April 1, 1998—just two days after Geneva obtained FDA approval of its Capsule ANDA—Abbott reached an agreement with Geneva to prevent generic terazosin from entering the market.	(See Ex. 2 at 28, ¶ 178; Ex. 4 at 9).
20. In exchange for Abbott's monthly payment of $4.5 million, Geneva agreed not to market its generic terazosin until the earliest of (1) the sale of generic terazosin by another manufacturer; (2) entry of	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1040; (see also Ex. 2 at 28, ¶¶ 178-85; see also Ex. 4 at 10).

ADDITIONAL FACT	SUPPORTING EVIDENCE
a final, unappealable judgment concerning the validity of the '207 patent; or (3) February 17, 2000 (the date one of Abbott's other patents expired).	
21. During this time, Abbott's infringement suit against Geneva in response to Geneva's ANDA for a tablet form of terazosin continued.	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1040; (see also Ex. 2 at 24, ¶ ¶ 145-46; see also Ex. 4 at 8-9).
22. In its suit against Abbott, Geneva contended that the '207 patent was invalid under the "on-sale bar" of 35 U.S.C. § 102(b) because the form of terazosin covered by the '207 patent had been sold in excess of three times more than a year before Abbott filed the '207 patent.	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1040-41; (see also Ex. 2 at 19, ¶ 114; Ex. 4 at 9, 31).
23. Abbott reached a similar, multi-million-dollar-per-month agreement with Zenith-Goldline ("Zenith"), another manufacturer seeking to market generic terazosin, pursuant to which Zenith could market generic	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1040; (Ex. 1 at 6).

ADDITIONAL FACT	SUPPORTING EVIDENCE
terazosin on February 17, 2000 or the date another generic manufacturer began to sell generic terazosin, whichever occurred first.	
24. The court rejected Abbott's argument that the "on-sale bar" did not apply because the purchasers did not know that the version of the terazosin they had purchased was the specific crystalline polymorph covered by the '207 patent.	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1041; (see also Ex. 4 at 8-9)
25. The district court, and ultimately the Federal Circuit, agreed with Geneva that "knowing" use was not required (citing the very case that Abbott had chosen to omit from its patent submission) and declared Abbott's '207 patent invalid.	Kaiser Found. Health Plan v. Abbott Labs., 552 F.3d at 1041; Abbott Labs. v. Geneva Pharms., Inc., 182 F.3d 1315, 1317-19 (Fed. Cir. 1999), cert. denied, 528 U.S. 1078 (2000).
26. No longer constrained by the risk of infringing the '207 patent, Geneva entered the market and began selling generic terazosin in capsule form the very next month.	(Ex. 2 at 29, ¶187; Ex. 4 at 11).

ADDITIONAL FACT	SUPPORTING EVIDENCE
27. Before generic terazosin came to market in August 1999, Abbott was the only seller of a pharmaceutical product containing the active ingredient terazosin.	(Ex. 2 at 27 ¶ 168).
28. Hytrin was extremely lucrative for Abbott, generating $540 million in annual sales and representing more than 20% of its domestic pharmaceutical sales.	Request for Judicial Notice ¶ 3, Ex. (Abbott's Resp. to Req. for Admissions at 5, Resp. No. 6); Ex. 1 at 2).
29. Abbott's internal models and memoranda show that it was fully aware that the entry of generic terazosin into the market would have a catastrophic effect on sales volume and revenue.	(Vieux Decl. ¶ 1, Ex. A).
30. These models and memoranda predicted that within just two months of generic terazosin's coming to market, Abbott's Hytrin sales would plummet 40% and after a year would fall over 80%.	(Vieux Decl. ¶ 1, Ex. A).
31. Before the Federal Circuit ruled that the '207 patent was invalid, Abbott had been able to sell	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Ex. 2 at 27, ¶ 170).

ADDITIONAL FACT	SUPPORTING EVIDENCE
Hytrin to Kaiser in large volumes for approximately $0.70 per tablet	
32. In August 1999, after the Federal Circuit declared the '207 patent invalid and Geneva entered the market, Abbott could no longer maintain its supracompetitive price and offered to sell Hytrin to Kaiser for just $0.10 per tablet—an 86% reduction in price.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Ex 2 at 27, ¶ 171).
33. Kaiser refused Abbott's offer and began to purchase generic terazosin from Geneva	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Ex. 2 at 27, ¶ 172.)
34. The $0.70-per-tablet price Abbott charged Kaiser prior to Geneva's entering the market was a supracompetitive price, for Abbott determined that the competitive price for Hytrin was only $0.10 per tablet once competition actually existed.	(Vieux Decl. ¶ 4, Ex. D (J. Cercy Dep. Tr. 141:1-15 (Sept.17,203)); Ex. 2, ¶¶170-71).
35. In July 1999, the month before Geneva entered the market with generic terazosin, Abbott sold nearly 35 million units of Hytrin for total revenue of approximately	(Vieux Decl. ¶ 2, Ex. B).

ADDITIONAL FACT	SUPPORTING EVIDENCE
$43 million.	
36. On March 22, 2002, Kaiser sued Abbott, among others, in this Court, asserting claims under Sections 1 and 2 of the Sherman Act and analogous provisions of California law.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (see Request for Judicial Notice ¶6, Ex. 6, Dkt. No. 1).
37. By August 2000, one year after Geneva began to sell generic terazosin, Hytrin sales had fallen to 11.4 million units for a total revenue of under $10.4 million—a 76% drop.	(Vieux Decl. ¶ 2, Ex. B).
38. It is thus undisputed that, with the advent of competition from generic terazosin, Abbott's sales volume and revenues for Hytrin plummeted from 35 million units and $45 million in July 1999 to just 11 million units and $10 million in August 2000.	(Vieux Decl. ¶ 2, Ex. B).
39. Notwithstanding the fact that Kaiser had purchased Hytrin in large volumes, it was still forced to pay the supracompetitive price of $0.70 per tablet until generic	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Ex. 2 at 27, ¶¶ 170-71).

ADDITIONAL FACT	SUPPORTING EVIDENCE
terazosin entered the market.	
40. On March 22, 2002, Kaiser sued Abbott, among others, in this Court, asserting claims under Sections 1 and 2 of the Sherman Act and analogous provisions of California law.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Request for Judicial Notice ¶ 6, Ex. 6, Dkt. No. 1).
41. Kaiser's Section 2 claim alleged that Abbott illegally sought to enhance its monopoly power and delay the entry of generic drug competition by filing sham lawsuits and also by fraudulently obtaining the '207 patent, otherwise known as Walker Process fraud	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1044; (Ex. 6 at 2-3).
42. In 2003, Kaiser's suit was transferred to a multi-district panel of the United States District Court for the Southern District of Florida ("MDL Court") and consolidated, for purposes of pretrial proceedings, with similar suits involving terazosin brought by other plaintiffs ("MDL").	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Request for Judicial Notice ¶ 7, Ex. 7, Dkt. Nos. 19-20).
43. On August 31, 2004, the MDL	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; Ex. 5, In Re

ADDITIONAL FACT	SUPPORTING EVIDENCE
Court granted summary judgment in favor of Abbott on Kaiser's Sherman Act Section 2 claim, holding that the Noerr-Pennington doctrine applied and immunized Abbott from antitrust liability based on (1) its multiple infringement suits against generic manufacturers of terazosin; and (2) Abbott's procurement of the '207 patent through fraud on the PTO.	Terasozin Hydrochloride Antritrust Litig., 335 F. Supp. 2d 1336, 1370 (S.D. Fla.2004).
44. Accordingly, the MDL Court denied as moot Kaiser's motion for summary judgment with respect to Abbott's monopoly power.	Ex. 5, In Re Terasozin Hydrochloride Antritrust Litig., 335 F. Supp. 2d at 1341 n.l.
45. Nevertheless, the MDL Court later observed that "the Court [wa]s persuaded that Abbot[t] ha[d] power in the relevant market, which is the market for Hytrin and its generic bioequivalent forms of terazosin hydrochloride," noting the fact that Abbott would pay a generic	(Ex. 4 at 55 n.40).

ADDITIONAL FACT	SUPPORTING EVIDENCE
manufacturer an exclusion payment "indicate[s] that the pioneer [Abbott] exercises substantial power in the market."	
46. In February 2005, the MDL Court transferred this action back to this Court for trial on the issues of causation and damages for Kaiser's Sherman Act Section 1 claim	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Request for Judicial Notice ¶ 8, Ex.8 (Dkt. No. 22)).
47. The MDL Court already had ruled that the Geneva Agreement was a *per se* violation under Section 1 of the Sherman Act and had entered partial summary judgment on liability in favor of Kaiser on its Section 1 claim.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Ex. 1 at 9, 56).
48. After a trial in March and April of 2006, the jury found in favor of Abbott on both issues.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Request for Judicial Notice ¶, Ex. 9 (Dkt. No. 204)).
49. Following the jury verdict, Kaiser appealed the MDL Court's grant of summary judgment on its Sherman Act Section 2 claim as well as this Court's judgment in favor of Abbott on Kaiser's	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1042; (Request for Judicial Notice ¶ 10, Ex. 10 (Dkt. No 214)).

ADDITIONAL FACT	SUPPORTING EVIDENCE
Sherman Act Section 1 claim to the United States Court of Appeals for the Ninth Circuit.	
50. The Court of Appeals affirmed this Court's judgment on Kaiser's Sherman Act Section 1 claim and the MDL Court's summary judgment on Kaiser's "sham litigation" claim, but reversed as to MDL Court's summary judgment on Kaiser's Walker Process fraud claim.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1042; (Ex. 10).
51. The Court of Appeals held that there was sufficient evidence for a jury to find that Abbott's conduct before the PTO with respect to the '207 patent was fraudulent and remanded the matter to this Court for trial.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1042; (Ex. 10).
52. Before generic terazosin came to market, Abbott was the only seller of a pharmaceutical product containing the active ingredient terazosin.	(Ex. 2 at 27, ¶ 168).
53. One of the experts retained by Abbott in the MDL proceedings	(Vieux Decl., Ex. C).

ADDITIONAL FACT	SUPPORTING EVIDENCE
estimated that Abbott's monthly profits would have dropped $22-25 million per month over the fifteen-month period following Geneva's coming to market in April 1998.	
54. Once the Geneva Agreement terminated, Geneva began selling generic terazosin in August 1999, and Abbott offered to sell Hytrin to Kaiser for just $0.10 per tablet—an 86% reduction in price.	Kaiser Found. Health Plan v. Abbott Labs., 552 F. 3d at 1041; (Ex. 2 at 27, ¶ 172)

Dated: August 25, 2009

Respectfully submitted,

BLANK ROME LLP

By: /s/ Ann B. Laupheimer
ANN B. LAUPHEIMER (*pro hac vice*)
JOSEPH M. PROFY (*pro hac vice*)
One Logan Square
130 North 18th Street
Philadelphia, Pennsylvania 19103-6998
Telephone: 215.569.5500
Facsimile: 215.569.5555
E-mail: laupheimer@blankrome.com
profy@blankrome.com

W. SCOTT SIMMER (*pro hac vice*)
HARDY VIEUX (*pro hac vice*)
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037
Telephone: 202.772.5800
Facsimile: 202.772.5858
E-mail: simmer@blankrome.com
vieux@blankrome.com

Attorneys for Kaiser Foundation Health Plan, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 25th day of August 2009, I electronically filed the foregoing Statement of Uncontroverted Facts and Conclusions of Law in support of Plaintiff's Motion for Partial Summary Judgment Motion on Monopoly Power with the Clerk of the Court using the CM/ECF system.

By: Linda Sepulvado
Linda Sepulvado